

CLAIMS

1. A dry powder composition comprising recombinant human alpha 1-antitrypsin (rAAT).
2. The dry powder composition of claim 1, that has not been subjected to
5 viral inactivation.
3. The dry powder composition of claim 1 or claim 2, whose protein content is less than 10%, more preferably less than 5%, most preferably less than 1% α1-antichymotrypsin.
4. The dry powder composition of any preceding claim, whose protein
10 content is less than 10%, more preferably less than 5%, most preferably less than 1% albumin.
5. The dry powder composition of any preceding claim, whose protein content is less than 10%, more preferably less than 5%, most preferably less than 1% human protein.
- 15 6. The dry powder composition of any preceding claim, whose protein content is more than 90% rAAT.
7. The dry powder composition of claim 6, whose protein content is more than 95% rAAT.
8. The dry powder composition of claim 6, whose protein content is more
20 than 99% rAAT.
9. The dry powder composition of any preceding claim, further comprising 1 to 2000 milliequivalents salt per 100 mg of rAAT, more preferably 50-500 milliequivalents, most preferably 100-200 milliequivalents.
10. The dry powder composition of any preceding claim, that is free of sugar.
- 25 11. The dry powder composition of any preceding claim, that contains less than 1% water.
12. The dry powder composition of claim 11, that contains less than 0.5% water.
13. The dry powder composition of any preceding claim, that retains at least
30 80% of initial rAAT activity, preferably more than 90%, upon storage at under conditions that are, or are equivalent to, 50°C for 3 months.
14. The dry powder composition of any preceding claim, that retains at least

80% monomeric rAAT, preferably > 95% monomer, upon storage under conditions that are, or are equivalent to, 50°C for 3 months.

15. The dry powder composition of any preceding claim, further comprising a reducing agent, such as glutathione, cysteine, dithiothreitol or N-acetyl cysteine.
16. The dry powder composition of any preceding claim, further comprising an antioxidant, such as ascorbic acid or L-methionine.
17. The dry powder composition of any preceding claim, further comprising a buffer, such as histidine, phosphate or citrate.
- 10 18. The dry powder composition of claim 17, wherein the buffer is such that, on reconstitution of the composition in water, the reconstituted solution has a pH of from about 6 to 9, more preferably 6.5-8, preferably from 6.8-7.0.
19. The dry powder composition of any preceding claim, further comprising a chelating agent, such as EDTA or citrate.
- 15 20. The dry powder composition of any preceding claim, further comprising a surfactant such as polyoxyethylene sorbitan oleate.
21. The dry powder composition of claim 1, that consists essentially only of rAAT and the components defined in claims 9, 15, 16, 17, 19 and 20.